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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,072	12/01/2003	David J. Mooney	99-32	2596

26161 7590 04/11/2006

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EXAMINER	
NAFF, DAVID M	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,072	MOONEY ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/1/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims examined on the merits are 1-20, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by claim 10 requiring a tissue engineering method, and not requiring the steps carried out to produce tissue.

Claim 11 is confusing and unclear as to how it further limits claim 10. Claim 11 requires culturing both types of cells after being seeded onto the matrix to produce expanded cell populations. Claim 10 requires culturing after the cell types are seeded on the matrix, and this culturing would appear to expand the cell types. If the cell types are already expanded in claim 10, claim 11 does not further limit claim 10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 10, 11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Vyakarnam et al (6,534,084 B1).

Claim 1 is drawn to a cell-containing implant comprising a polymeric matrix and a mixture of cells comprising smooth muscle cells and at least one other cell type. Claims 10, 11 and 15 are drawn to a tissue engineering method comprising seeding the polymer matrix with the mixture of cells and culturing the mixture of cells.

Vyakarnam et al disclose providing a polymeric foam having microstructural variations in structure mimicking the anatomical features of tissue such as cartilage, skin or bone (col 2, lines 55-58), and its us as a scaffold for tissue engineering (col 5, lines 25-34, and paragraph bridging cols 18 and 19). The foam can be seeded with a combination of different cell types, which can be smooth muscle cells and endothelial cells (col 3, lines 15-22, and col 9, lines 20-24), or other combinations of cells (col 19, lines 1-10, and col 32,

lines 7-12). The foam can be seeded with the cells and cultured (col 31, lines 61-64). The foam is bioabsorbable (col 32, line 33).

Vyakarnam et al disclose a cell-containing implant and tissue engineering method that are the same as presently claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 4, 12, 14, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al in view of Vacanti et al (5,041,138).

Claim 3 requires an angiogenic compound to be present and claim 4 requires the matrix to be coated with a polymer. Also claimed is the matrix having various shapes (claim 14), and expanding the cells prior to seeding the matrix (claim 12). Claim 16 requires a method of treating a patient by implanting the matrix containing the mixture of cells in the form of a construct that provides structural support. Claim 19 requires producing the matrix as a solid block and altering the shape before or after seeding with a mixture of cells.

Vyakarnam et al is described above.

Vacanti et al disclose culturing chondrocytes in a matrix for implanting to produce cartilage (col 4, lines 40-55). Structural and functional cartilage equivalents are provided (col 5, lines 7-10). Chondrocytes are cultured on the matrix *in vitro* before mplanting, if insufficient numbers are available for implantation (col 3, lines 21-43, and col 5, lines 41-50). When an adequate number of cells are present, the cells can be attached to the matrix and implanted directly, without proliferation *in vitro* (col 3, lines 34-37). The matrix can be a rigid structure (col 11, lines 37-38), or a flexible structure that can be conformed to a joint surface (col 11, lines 39-40). More than one cell line can be attached to the matrix such as by attaching bone and chondrocyte cell populations. The matrix can contain angiogenic compounds (col 5, lines 50-55) for vascularizing,

and be coated with polymers that can be agar, agarose, gelatin or gum arabic to enhance cell attachment (col 5, lines 63-68).

It would have been obvious to modify the matrix of Vyakarnam et al by providing the matrix with an angiogenic compound and a polymer coating to obtain the function of the angiogenic compound to vascularize the matrix and the polymer coating to enhance cell attachment as suggested by Vacanti et al. A matrix shape as required by claim 14 would have been obvious to provide the shape of a defect being repaired. Expanding cells prior to seeding the matrix as in claim 12 would have been obvious to obtain a sufficient number of cells to seed the matrix so the matrix can be implanted without expanding after seeding. Implanting the matrix of Vyakarnam et al when containing a mixture of cells as required by claim 16 would have been suggested by Vacanti et al implanting a matrix that can contain a mixture of cells. Forming the matrix as a block and then altering the shape as in claim 19 would have been obvious from Vacanti et al disclosing a flexible matrix that can be conformed to a joint structure. Producing the matrix of Vyakarnam et al in rigid form as suggested by Vacanti et al will result in the matrix providing structural support.

Claim Rejections - 35 USC § 103

Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 3, 4, 12, 14, 16 and 19 above, and further in view of Shastri et al (6,471,993 B1).

Claim 18 require determining shape of the matrix by CAT scan or MRI imaging. Claim 20 requires the shape of the matrix to be fabricated by hand or by computer aided design-computer aided manufacturing (CAD-CAM) systems.

Shastri et al disclose using CAT-scan image in combination with CAD/CAM to create a scaffold for tissue engineering of the desired shape (col 1, lines 41-43, and col 16, lines 58-63).

When forming the matrix of Vyakarnam et al containing a mixture of cells, and implanting the matrix as suggested by Vacanti et al as set forth above, it would have been obvious to shape the matrix using CAT-scan image in combination with CAD/CAM as taught by Shastri et al.

Claim Rejections - 35 USC § 103

Claims 2, 5-9, 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 3, 4, 12, 14, 16 and 19 above, and further in view of Purchio et al (5,902,741).

Claims 2 and 13 require at least one other cell type to be chondrocytes or osteoblasts, and structural support to be provided by the implant or tissue. Claim 17 requires at least one other cell type to include cartilage-forming cells and forming a cartilaginous structure member. Claims 5-7 require an implantable structural member comprising the polymeric matrix containing a mixture of cartilage-forming cells and smooth muscle cells, which is a structural member when implanted. Claim 8 requires the structural member to comprise an angiogenic compound and claim 9 requires a polymer coating on the matrix of the member.

Purchio et al disclose producing cartilage tissue *in vitro* by culturing cartilage-producing stromal cells inoculated onto a three-dimensional framework (col 6, lines 8-32) formed of a polymeric matrix (paragraph bridging cols 10 and 11, and col 11, lines 30-41). The cultured cells can be implanted *in vivo* (col 13, lines 18-20, and col 15, lines 40-50). The cartilage-producing stromal cells can include a combination of cells including chondrocytes and muscle cells (col 26, lines 31-35).

When forming the matrix of Vyakarnam et al containing a mixture of cells, and implanting the matrix as suggested by Vacanti et al as set forth above, it would have been obvious to culture smooth muscle cells in combination with chondrocytes (cartilage-forming cells) as suggested by Vyakarnam et al disclosing chondrocytes and muscle cells that can be used in combination, and as suggested by Purchio et al disclosing producing cartilage by culturing a combination of cells that can include chondrocytes and muscle cells seeded on a polymeric matrix. It would have been obvious to produce the matrix of Vyakarnam et al in rigid form as suggested by Vacanti et al, and the matrix in rigid form will inherently provide structural support. Moreover, cartilage tissue is inherently capable of providing structural support. An angiogenic compound as required by claim 8 and polymer coating as required by claim 9 would have been suggested by Vacanti et al for reasons set forth above.

Claim Rejections - 35 USC § 103

Claims 1-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purchio et al in view of Vyakarnam et al and Vacanti et al.

The invention and references are described above.

It would have been obvious to use smooth muscle cells as the muscle cells in the combination of chondrocytes and muscle cells suggested by Purchio et al for producing cartilage as suggested by Vyakarnam et al disclosing culturing smooth muscle cells in combination with another cell type on a matrix to produce tissue and as further suggested by Vacanti et al disclosing culturing multiple different cell populations on a matrix to produce cartilage. The conditions of dependent claims and providing a structural support or member would have been obvious from the references for reasons set forth above.

Claim Rejections - 35 USC § 103

Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-17 and 19 above, and further in view of Shastri et al.

The use of CAT scan and CAD-CAM for shaping the matrix as claimed would have been obvious from Shastri et al for reasons set forth above when applying Shastri el al.

Conclusion

Vyakarnam et al (6,306,424 B1) (col 3, lines 15-20) and Vacanti et al (5,770,417) (claim 10) are made of record to further show

culturing a combination of different cell types on a matrix for implanting.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
4/8/06